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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gianluca Gazza

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EXAMINER

DORNBUSCH, DIANNE

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

06/29/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,973	<b>Applicant(s)</b> GAZZA, GIANLUCA	
	<b>Examiner</b> DIANNE DORNBUSCH	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 72,73,75,78-82,87,91,92,95,96,98-100,105 and 142-164 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 72,73,75,78-82,87,91,92,95,96,98-100,105 and 142-164 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: on page 3 lines 15-19, claims 1 and 34 are referred to but they no longer exist.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 72, 73, 75, 78, 79, 81, 87, 96, 100, 105, 154-156, and 162-164 are rejected under 35 U.S.C. 102(b) as being anticipated by Ressemann et al. (5,549,553). Ressemann discloses the following claimed limitations:

Claims 72, 105, 154, and 164: An inflatable balloon (28) structure for catheters (Fig. 1), the balloon structure being of predominant longitudinal extent with a proximal end and a distal end (Fig. 2), and being suitable for performing an expansion in an object to be dilated (Fig. 1-2), the balloon structure comprising a proximal shank, a distal shank and an intermediate portion between said proximal and distal shanks (see figure below), said balloon structure, including the proximal and distal shanks, having a wall (see figure below) which, when the inflation chamber is expanded, has an outer surface of circular cross-section transverse to the longitudinal extent of the balloon structure, and an inner surface which delimits an inflation chamber (see figure below), in which

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at least one wall cavity (52) is provided in the wall between the outer surface and the inner surface (see figure below), the wall cavity extending without interruptions and/or openings, longitudinally relative to the balloon structure, between the distal end and at least a portion of the proximal shank (Fig. 2), the wall cavity following the balloon structure outline from the distal end to at least a portion of the proximal shank (Fig. 2), said wall cavity, suitable for housing a guide wire (30), defines a guide wire lumen between the distal end and at least a portion of the proximal shank (Fig. 2), the wall cavity has an opening which forms a guide wire lateral opening to allow a guide wire to be inserted in the wall cavity or to emerge therefrom (Fig. 2).

Claims 73 and 155: That when the balloon structure is inflated or expanded, the outer surface of the intermediate portion is free of protuberances or recesses (Fig. 2).

Claims 75 and 156: That the balloon structure is inflated or expanded, the outer surface of the intermediate portion is cylindrical (Fig. 2b).

Claim 78: That the balloon comprises a proximal tubular portion (see figure below) in the vicinity of the proximal end (see figure below).

Claim 79: That the proximal shank (see figure below) connecting the proximal tubular portion and an intermediate portion (see figure below).

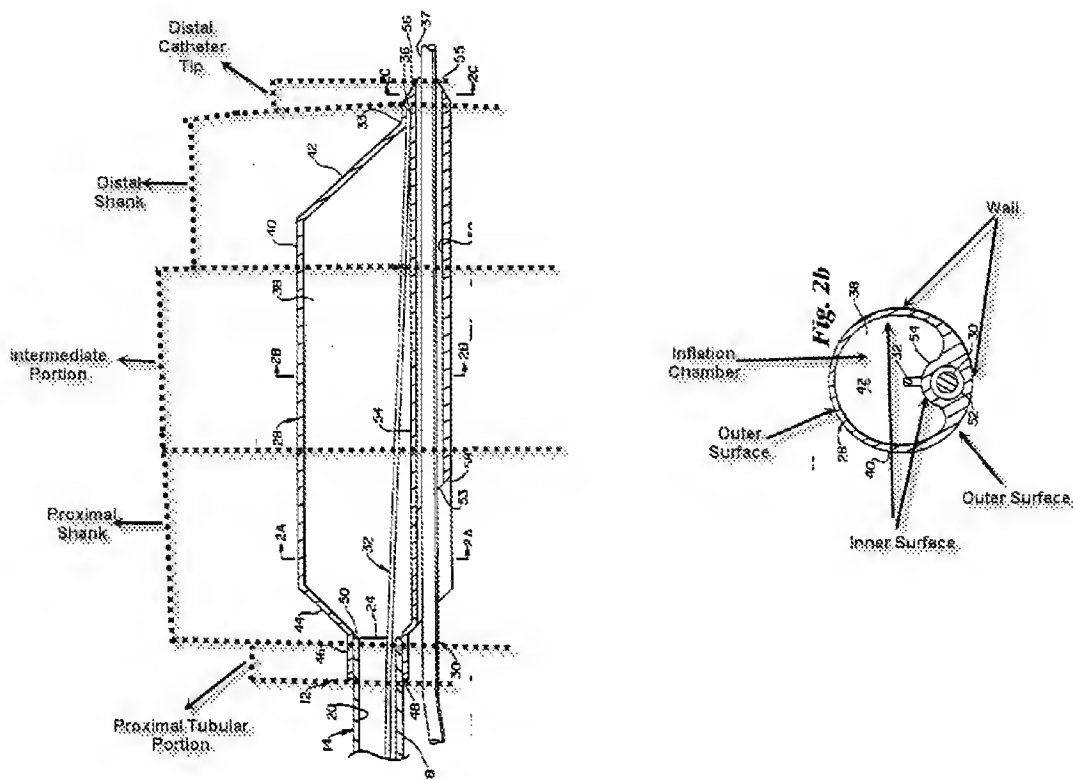
Claim 81: That the distal connecting shank (see figure below) between the intermediate portion and a portion for connection to a distal catheter tip (see figure below).

Claim 87: The structure is produced from an extruded tube (Fig. 3) having at least two cavities (Fig. 3-5c), one of which is deformed to form the inflation chamber of the balloon structure (Fig. 3-5c and Col. 8 Lines 1-60).

The claimed phrase “produced from an extruded tube having at least two cavities” is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Claims 96 and 162: The wall cavity is coated with or delimited by a layer of material with a coefficient of friction such as to facilitate sliding of a guide wire housed in the wall cavity (Col. 7 Lines 59-63).

Claims 100 and 163: That the inflation chamber is closed in a leak tight manner (there cannot be any leaks since it would cause the balloon to not completely inflate) onto an apex tip (Fig. 2), leaving solely openings for access to one or more guide-wire cavities (Fig. 2).



***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 80, 82, 98, 99, 143-147, 151-153, 157, and 158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann et al. (5,549,553).

Claims 80, 82, 146, 147, 157, and 158:

Ressemann discloses the claimed invention except for the internal taper angle of the proximal and distal shank ranges from 20-40 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a tapered angle between 20 to 40 degree, preferably 30 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 98 and 99:

Ressemann discloses the claimed invention except for the thickness of the wall portion separating the wall cavity and the inflation chamber when the balloon structure is inflated/expanded is between 55% and 100% (claim 98) or between 60% and 70% (claim 99) of the thickness of the wall portion that separates the wall cavity from the outer surface. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the wall portion separating the wall cavity and the inflation chamber to have a thickness between 55% and 100% or 60% and 70% of the of the wall portion that separates the wall cavity from the outer surface, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 143-145 and 151-153:

Ressemann discloses the claimed invention including that the wall cavity can coextend with the entire length of the balloon such that the proximal end (58) of the wall

cavity terminates at the proximal end of the balloon (Fig. 7-8 and Col. 7 Lines 55-59).

Furthermore, Ressemann shows that the wall cavity can extend passed the distal end of the balloon where the distal opening is distal of the balloon.

However Resseman does not disclose that the proximal opening of the wall cavity is at a direction proximal from the balloon. It would have been obvious to one having ordinary skill in the art at the time the invention was made place the aperture proximal from the balloon, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

6. Claims 91, 92, 95, 148-150, and 159-161 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann et al. (5,549,553) in view of Shonk (5,304,135).

Ressemann teaches that the balloon structure comprises a polymer (Col. 6 Lines 55-60) and is produced by expansion of an inflation cavity of a tube (60) with at least two cavities (Fig. 3-5c and Col. 8 Lines 50-52).

The claimed phrases describing the method of making the balloon structure such as the method of producing the balloon structure through a co-extruded tube are being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Ressemann teaches all the claimed limitations discussed above however, Ressemann does not disclose that the tube that is used to form the balloon structure comprises two



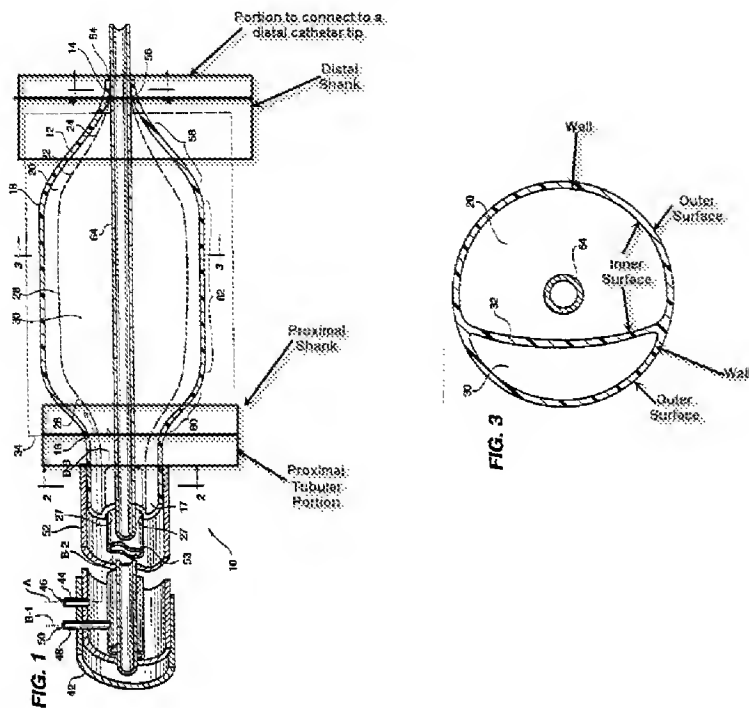
materials nor the specifications of this materials .

Shonk discloses an inflatable balloon structure (12) for catheters, the balloon structure being of predominant longitudinal extent with a proximal end (16) and a distal end (14), and being suitable for performing an expansion in an object to be dilated (Fig. 1), the balloon structure comprising a proximal shank (see figure below), a distal shank (see figure below) and an intermediate portion (18) between said proximal and distal shanks (see figure below), said balloon structure including the proximal and distal shanks, having a wall (see figure below) which, when the inflation chamber is expanded, has an outer surface (see figure below) of circular cross-section transverse to the longitudinal extent of the balloon structure (see figure below), and an inner surface (see figure below) which delimits an inflation chamber (20), in which at least one wall cavity (30) is provided in the wall (Fig. 3) between the outer surface and the inner surface (see figure below), the wall cavity extending without interruptions and/or openings, longitudinally relative to the balloon structure, between the proximal end and the distal end, the wall cavity following the balloon structure outline from the proximal end to the distal end (Fig. 1).

Shonk further teaches that the balloon structure comprises a polymer (Col. 5 Lines 5-20) with at least two cavities (Fig. 3); the balloon structure having two to three materials (Col. 5 Lines 5-20); that the material that delimits the inflation cavity is a material that is semi-compliant (since the this material is the outer wall of the balloon it is compliant in order to allow the balloon to inflate to a maximum point); that the second material forms the wall portion which separates the wall cavity from the outer surface

(Fig. 3) and has a greater flexibility than the first material (if the first material is the material that delimits the inflation cavity, then when the balloon is inflated it reaches a maximum where it is not as flexible as the second material).

Note that Shonk teaches all the limitations discussed above but is silent as to the method of making the balloon structure. The claimed phrases describing the method of making the balloon structure such as the method of producing the balloon structure through a co-extruded tube are being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.



It would have been obvious to one having ordinary skill in the art at the time the invention was made to use two different material on the tube, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Ressemann with a two different materials on the tube view of the teachings of Shonk, in order to provide the device with structure flexibility and stability at different locations throughout its length.

***Response to Arguments***

7. Applicant's arguments filed April 19, 2010 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DIANNE DORNBUSCH** whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./  
Examiner, Art Unit 3773

/TODD E. MANAHAN/  
Supervisory Patent Examiner, Art Unit 3734